The Michigan Department of Community Health
Institutional Review Board for Human Subjects Research
Capitol View Building, 7th Floor, 201 Townsend Street, Lansing, MI 48913
Phone: 517/241-1928 Fax: 517/335-8297

MDCH IRB REVIEW APPLICATION

Authority: Code of Federal Regulations Title 45 Part 46

Completion of Sections 1-4 is mandatory for all applications. Note: To complete this application, type answers directly into shaded answer areas. To check a box, put your cursor on the box, double click and choose "checked."

SECTION 1 – PROJECT IDENTIFICATION (completion of this section is mandatory)

1.1 **Title of the Project** (title must be the same on all study documents):

1.2 **"Responsible MDCH Employee"** (MDCH employee responsible for the Department's role in this research):

1.3 **"Responsible MDCH Employee's" Signature:** (required to assure departmental responsibility for the protection of human subjects and adherence to MDCH IRB requirements):

_____

1.4 **"Responsible MDCH Employees's" Agency and Bureau, Office, or Center:**

1.5 **Source of Funding** (include both the name and type of agency, e.g., CDC-federal):

1.6 **Grant Number (REQUIRED** for all federally funded projects):

1.7 **Project Type** (Check all that apply)

- ☐ Direct human subject participation involving invasive treatments, procedures, or experimentation.
- ☐ Direct human subject participation using surveys, interviews, focus groups, observations, etc.
- ☐ Indirect human subject participation using human data or biological specimens that were collected, or will be collected, for non research purposes, or material that will be discarded.

1.8 **Check which FDA-regulated test articles (i.e., investigational drugs, biologics or devices) will be used in this project?** (Check all that apply)

- ☐ No test article used
- ☐ Drug or biologic used IND#: Trial Phase:
- ☐ Device used IND#: Risk level (significant or insignificant):

1.9 **What is the projected date to begin this research?**

1.10 **What is the projected date to complete this research?**

1.11 **List any other IRBs that will review this project:**

1.12 **Describe any potential conflicts of interest between the researchers and the study sponsors:**

1.13 **Name of Principal Investigator (if not the responsible MDCH employee listed in 1.1):**

**********END OF SECTION 1**********

SECTION 2 – APPLICATION TYPE (completion of this section is mandatory)

2.1 Does the research involve direct human subject participation? ☐ YES ☐ NO

If **YES**, complete Sections 1-10 **AND** check other sections below that apply to the research. If **NO**, skip to 2.2.

☐ Surveys, interviews, focus groups, observations, etc. – **complete also Section 11**.

☐ Blood removal – **complete also Section 12**.

☐ Tissue removal; investigational drugs, biologics or devices; approved drugs, biologics or devices; ionizing radiation; organ/tissue/cell transfer; gene transfer – **complete also Section 13**.

☐ Genetic analysis **– complete also Section 14**.

☐ Project will use existing human-derived data or biological specimens, previously collected or to be collected in the future for non research purposes, or to be discarded – **complete also Section 15**.

2.2 Does the research involve only indirect human subject participation? ☐ YES ☐ NO

If **YES**, complete Sections 1-4 **AND** Section 15.

**************************************END OF SECTION 2**************************************

SECTION 3 – RESEARCH INFORMATION (completion of this section is mandatory)

3.1 Provide a concise (300 words) summary of the research, including the following information:

FOR RESEARCH THAT INVOLVES DIRECT HUMAN SUBJECT PARTICIPATION

- Age, gender, ethnicity, and race distribution of the study population, including vulnerable populations
- What will be done to the participants for research purposes
- Whether or not the research records will be linkable in any way to the research participants
- Informed consent process to be employed

FOR RESEARCH THAT DOES NOT INVOLVE DIRECT HUMAN SUBJECT PARTICIPATION

- Information on the kind and source of data or biological specimens
- What will be done with data or biological specimens
- How data will be linkable to the persons from whom the data or biological specimens are derived
- Informed consent process to be employed

(Type 300 word summary here)

3.2 What documents are you submitting with this application? Check only those that are applicable.

☐ Study protocol

☐ Informed consent instrument(s)

☐ Investigator's brochure, solicitation materials for subject recruitment (specify):

☐ Survey instruments

☐ HIPPA-Compliant Request Form for waiver of authorization

☐ IRB review/approval documents from institution of principal investigator, if not MDCH

☐ Other (specify):

3.3 If you believe that this project qualifies for one of the exemptions in 45 CFR 46.101(b) (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101) please indicate here the specific exemption:

3.4 If you believe that this project is public health surveillance or practice, rather than human subjects research, please explain (refer to Council of State and Territorial Epidemiologists report "Public Health Practice vs. Research" (http://www.cste.org/pdffiles/newpdffiles/CSTEPHResRptHodgeFinal.5.24.04.pdf) by James Hodge and Lawrence Gostin):

**************************************END OF SECTION 3**************************************

SECTION 4 – INFORMED CONSENT PROCESS (completion of this section is mandatory)

4.1 Check the type(s) of informed consent process that will be used? Check all that apply.

☐ A comprehensive written document, signed by the participant (or legal representative).

☐ A comprehensive written document, that is not signed (justify with criteria in 46.117(c).

☐ A short written document stating that all required elements have been presented orally to the participant (or legal representative) and signed by either of them (justify with criteria in 46.117(c)).

☐ The assent of children that documents their willingness to participate in research (required from children who are capable of comprehending the nature of the study).

☐ Check this box if you are asking not to use one of these standard informed consent processes and complete "4.2" below.

4.2 Check the appropriate box below if you will not use a standard informed consent process or if you do not plan to seek consent.

☐ Check this box to request to alter or waive the informed consent requirement in whole or in part. (The IRB may approve research that alters, some or all of the required elements of informed consent or waives the requirement for consent entirely. The provisions of 46.116**(that permit these exceptions must be explained when such exceptions are requested.) Please specify what waiver or alteration you are requesting and how your project satisfies each of the criteria in 46.116.

☐ Check this box if you are requesting a waiver of authorization to disclose "protected health information" under HIPAA for research purposes. If yes, please attach a HIPAA-compliant request for waiver of authorization.

☐ Check this box if you believe that informed consent is unnecessary because your project can be exempted as explained in **3.3**, or public health surveillance as explain in **3.4** of this application.

4.3 Submit texts of all project-specific informed consent instruments for approval by the MDCH IRB and indicate what consent documents are appended.

4.4 Check below who may act on behalf of the subject to give consent to participate in this research.

Check all that apply.

☐ The adult participate in the research himself/herself

☐ The legal guardian of the participant in the research

☐ The next-of-kin of an adult participant (specify relationship):

☐ One parent of a child who participates in the research

☐ **Only** both parents of a child who participates in the research

☐ The assent of a child who participates in the research

4.4 Specify the criteria to be used to determine whether or not assent to participate should be obtained if children are among the research participants.

Consult 45 CFR 46.116 and 46.117 – for guidance on the elements of informed consent.

Information must be presented in a manner that will enable someone to voluntarily decide whether or not to participate in the research. For assistance in preparing informed consent documents, please see "Guidelines for Informed Consent" located on the MDCH website.

The informed consent process requirements are found in 45 CFR 46.116 (**http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116)** and the documentation of informed consent requirements in 45 CFR 46.117 http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.117).

Informed consent is a process to protect the rights of human research participants and it should not be considered primarily a form to protect the researcher.

END OF SECTION 4

Sections (5-14) Are For Research That Involves Direct Human Subject Participation

SECTION 5 – CHARTACTERISTS OF HUMAN PARTICIPANTS

(Leave this section blank only if there is no direct human participation in the research)

5.1 What health/disease categories (e.g. health participants, diabetics, etc.) **are involved?**

5.2 How many participants in each health/disease category will be recruited?

5.3 What will be the total duration of involvement of a participant in the study?

5.4 Describe if the research involves a health problem that may be relevant to certain populations.

5.5 Provide justification for research limited to a particular age, gender, or ethnic or racial group.

5.6 Check which of the following vulnerable populations may be research participants?

☐ None

☐ Children (age <18 years)

☐ Mentally compromised or decisionally impaired persons (specify)

☐ Women with child-bearing (reproductive) potential

☐ Pregnant or lactating women

☐ Fetuses (*ex utero)*

☐ *In-vitro* fertilization

☐ Prisoners

5.7 Check which of the following populations that could be subject to coercion may be among the participants?

- ☐ None
- ☐ Economically (coercion may result from payments to participants) or educationally deprived
- ☐ Patients of the investigator
- ☐ Students of the investigator
- ☐ Employees of the investigator

5.8 Unless incidental, justify the inclusion of research participants considered vulnerable or susceptible to coercion.

5.9 What are the criteria for inclusion, and exclusion, of research participants?

END OF SECTION 5

SECTION 6 – PARTICIPANT RECRUITMENT PROCEDURES

(Leave this section blank **only if** there is no direct human participation in the research).

6.1 How (e.g., existing list, random) will potential research participants be identified for recruitment?

6.2 Where (e.g., at home, in a clinic) will the potential research participants be recruited?

6.3 How (e.g., phone call, brochure, letter) will the potential research participants be recruited?

6.4 If recruitment materials (e.g., advertisements, letters) are to be used, are they attached? ☐ YES ☐ NO

6.5 If the research involves a health problem that may have specific relevance to certain ethnic, racial, or other minority groups, what special measures will be taken to optimize recruitment of participants from these groups?

END OF SECTION 6

SECTION 7 – EXPERIMENTAL TREATMENTS and PROCEDURES

(Leave this section blank **only if** there is no direct human participation in the research).

7.1 Research that involves experimental procedures requires MDCH IRB approval of the study protocol.

The protocol document shall bear a date, and a title matching the title shown in this application. It should describe goals of the study, background information, specific aims, experimental design, statistical analysis of results, subjects of the research, risks and benefits of treatment or procedures, and significance of the outcomes. Indicate here if the protocol is attached. **Is the study protocol attached? ☐ YES ☐ NO**

7.2 Describe any participant compensation.

7.3 Describe (non survey) treatment/procedures participants will undergo for this research.

7.4 Will the participants complete any interviews or survey instruments, or attend group meetings for the purposes of this research? ☐ YES ☐ NO If **YES**, you must also complete Section 11.

7.5 Will blood be taken from the participants for the purposes of this research? ☐ YES ☐ NO
If **YES**, you must also complete Section 12.

7.6 Please state whether any of the following will apply for the purposes of this research:

Biological specimens (other than blood) will be taken from the participants; investigational, FDA-exempted drugs, biologics, or devices or FDA-approved drugs, biologics, or devices will be

administered or applied to the participants; organs, tissues or cells from other humans will be administered or applied to the participants: participants will be exposed to ionizing radiation; or genetic material will be transferred to participants in the course of the research? ☐ **YES** ☐ **NO**
If **yes**, to any of the questions above, provide information by completing the applicable parts of Section 13.

7.7 Will genetic analysis be performed on any biological specimen to be acquired in conjunction with this research? ☐ **YES** ☐ **NO** If **YES**, you must also completed Section 14.

**********END OF SECTION 7**********

SECTION 8 – RISKS AND BENEFITS OF THE RESEARCH

(Leave this section blank **only if** there is no direct human participation in the research).

8.1 To indicate your judgment of the overall research-related risk of harm to participants, choose ONE of the three levels below

☐ Minimal risk

☐ Moderate risk

☐ High risk

***** A minimal risk is considered one where the probability and magnitude of harm or discomfort anticipated in the research is not greater, in and of itself, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

8.2 What direct risks could participants face by participating in this research, and what measures will be taken to minimize each risk?

8.3 If "vulnerable populations" or populations susceptible to coercion are among the research participants, what additional measures will be taken to minimize risks that may affect them?

8.4 What indirect risks (if any) to the public or community could result from this research?

8.5 What potential direct benefits (if any) could this research provide participants?

8.6 What potential indirect benefits could this research provide the public or others?

**********END OF SECTION 8**********

SECTION 9 – RESEARCH RECORDS

(Leave this section blank **only if** there is no direct human participation in the research).

9.1 Will research records be linkable to the participants by any identifiers, including names, registration numbers, code numbers, etc., entered into the records? ☐ **YES** ☐ **NO** **(**If **NO**, skip to 9.3)

9.2 If information in the research records was revealed, could it place the participants (or others) at risk of criminal or civil liability, or be damaging to their financial standing, employability, or reputation? ☐ **YES** ☐ **NO**

9.3 Describe the procedures that will be taken to ensure the privacy of the participants and to preserve the confidentiality of private information, including any plans to seek a "Certificate of Confidentiality" or "Director's Medical Research Project" designation. (Privacy is the right of an individual to control his or her personal information whereas confidentiality is the obligation of the researcher to protect private information they receive).

**********END OF SECTION 9**********

SECTION 10 – COSTS OF THE RESEARCH

(Leave this section blank **only if** there is no direct human participation in the research).

10.1 Describe any and all costs that the participant could incur by their participation, including indirect costs such as insurance.

END OF SECTION 10

SECTION 11 – INTERVIEWS, SURVEY OR GROUP MEETINGS INVOLVING THE RESEARCH PARTICIPANTS

(Complete this section if your answer to Question 7.4 was "Yes").

11.1 Describe the methods that will be used to collect information relevant to this section.

11.2 What is the anticipated duration and number of the sessions to collect this information?

11.3 Describe the information that will be collected by interview, survey, or group meetings.

11.4 If information will be collected by telephone, explain the consent procedure.

11.5 How will the privacy of the participants be protected while collecting information?

11.6 Could revelation of collected information place the participant, or others, at risk of criminal or civil liability, or be damaging to their financial standing, employability, or reputation?
☐ **YES** ☐ **NO** If **YES**, explain.

11.7 How will the information be recorded? Check all applicable entries.

- ☐ Text entered by investigators
- ☐ Text entered by the subject
- ☐ Voice of the subject
- ☐ Image of the subject
- ☐ Other (specify):

11.8 Describe how any survey records (instruments, recordings, etc.) will be labeled or identified to provide a direct, or indirect link, to the participant.

11.9 Are survey instruments and letters of prior announcement of intent to contact attached? ☐ **YES** ☐ **NO**

END OF SECTION 11

SECTION 12 – BLOOD TO BE TAKEN FROM PARTICIPANTS FOR THE PURPOSES OF RESEARCH

(Complete this section if your answer to Question 7.5 was "Yes", otherwise leave blank.)

If genetic information is to be obtained from the blood, you must also complete section 14.

12.1 By what route and method will blood be taken for the purposes of this research?

12.2 State the number of times, the intervals, and the time-span over which blood will be taken?

12.3 What is the largest volume of blood to be taken from a participant during a single draw?

12.4 What is the total volume of blood to be taken from a participant during the entire project?

12.5 Describe the participant's right to financial benefit from research using his or her blood.

12.6 Describe the process for disposal of blood specimens, including all rights of the participant and obligations of the researcher, if there are plans to store the material for future use.

END OF SECTION 12

SECTION 13 – TISSUE TO BE TAKEN; INVESTIGATIONAL, FDA-EXEMPTED DRUGS, BIOLOGICS OR DEVICES; FDA-APPROVED, NON-INVESTIGATIONAL DRUGS, BIOLOGICS OR DEVICES; EXPOSURE TO IONIZING RADIATION; ORGANS, TISSUE OR CELLS TO BE ADMINISTERED; GENETIC MATERIAL TO BE TRANSFERRED

(Complete this section **only if** your answer to Question 7.6 was "Yes").

13.1 Provide any additional information appropriate for the special considerations of "Research that is Infrequently Sponsored by the MDCH." The special considerations for these types of research are discussed in Section 13 of the "Information and Instructions Regarding Research Approval" document, under 'RESEARCH WITH DIRECT INVOLVEMENT OF HUMAN PARTICIPANTS."

END OF SECTION 13

SECTION 14 – GENETIC ANALYSIS OF BIOLOGICAL SPECIMENS TO BE OBTAINED FROM RESEARCH PARTICIPANTS

(Complete this section if your answer to Question 7.7 was "**YES**.")

14.1 Describe the biological specimens that will be genetically analyzed.

14.2 What particular genetic information will be acquired?

14.3 What is the specific purpose of the genetic analysis?

14.4 Describe any potential risk the genetic information could pose to insurability, employability, or social esteem of the subject, or others.

14.5 Describe how any genetic information and material will be kept confidential and secure. (Confidentiality refers to protection from authorized disclosure whereas security applies to the spectrum of physical, technical, and administration safeguards to protect the integrity, availability, and confidentiality of both the genetic information and the biological material).

14.6 Describe the process for providing genetic information to the participant (include the option to know or not to know the results, circumstances involving genetic abnormalities or parenthood, and circumstances that constitute a moral obligation to inform the participant).

14.7 Describe the circumstances involving any provision for genetic counseling.

14.8 Describe the participant's right to any potential financial benefit that may result from research using his or her genetic material.

14.9 Describe the process for disposal of the biological material, including all rights of the participant and obligations of the researcher, if there are plans to store the material for future use.

END OF SECTION 14

END OF SECTIONS FOR RESEARCH WITH DIRECT INVOLVEMENT OF HUMAN PARTICIPANTS

SECTION 15 – RESEARCH THAT DOES NOT INVOLVE DIRECT HUMAN SUBJECT PARTICIPATION

Complete this section for research that uses: a) existing human data or biological specimens that were collected previously for a purpose other than this research, or b) human data or biological material that will be collected in the future for non research purposes. The biological material must be residual material or material that would otherwise be discarded.

(Please note that if the research involves both direct human subject participation and also a component that does not involve direct human subject participation, you must complete both the appropriate sections of 5-14 and section 15).

15.1 **State why and how the existing data or biological materials were collected, or how data or biological materials to be used in this research will be collected for non research purposes.**

15.2 **Were the existing data or specimens originally stored in a way that could reveal the identity of the person from whom the material originated?** ☐ YES ☐ NO (If **NO** skip to the checklist on page 10).

15.3 **Will the research records carry any identifiers that could link the information to the person, from whom the material originated?** ☐ YES ☐ NO (If **NO** skip to the checklist on page 10).

15.4 **What type of data and/or biological specimens will be used for research?**

15.5 **From how many persons did/will the data or biological specimens originate?**

15.6 **From what source(s) will the data or biological specimens be procured?**

15.7 **How will the investigators gain access to the data or biological specimens?**

15.8 **If the data or biological specimens were originally collected for non research purposes, have the persons from whom the material originated agreed that the material might also be used for research purposes?** ☐ YES ☐ NO

15.9 **Does use of the data or biological specimens involve information which, if revealed, could place someone at risk of criminal or civil liability, or be damaging to their financial standing, employability, or reputation?** ☐ YES ☐ NO

15.10 **How will the permission of the persons from whom the data or biological specimens originated be obtained to use the material for research purposes?**

15.11 **What measures will be taken to keep the research records confidential?**

15.12 **Describe any access that researchers will have to information that is not essential to the research, what will be done with this non essential information, and how it will be protected?**

15.13 **Could the research to be conducted on the data or biological specimens reveal information of potential benefit to the persons from whom the material originated?** ☐ YES ☐ NO If **YES**, describe plans to inform participants about their rights:

15.14 **Could the research lead to the development of a commercial product that may bring financial benefit to the investigators and/or the sponsor?** ☐ YES ☐ NO If **YES**, describe plans to inform participants about their rights:

**********END OF SECTION 15**********

MDCH IRB REVIEW REQUEST COMPLETENESS CHECKLIST

Completion of this section is mandatory. Numbers in parentheses refer to the sections of the application, where the corresponding issues appear.

For each item shown in the following list the applicant should check off the cell to the left of each applicable item to indicate that it has been carried out and/or submitted. The column to the right is for MDCH IRB use only.

Investigator Completes		MDCH IRB
☐	Documents are dated to indicate the latest revisions.	
☐	The same project title is on the application, the study protocol and the informed consent documents.	
☐	Name of the "Responsible MDCH Employee" is shown.	
☐	"Responsible MDCH Employee's" signature appears on printed copies (1.2).	
☐	Printed copies of all project-specific consent instruments submitted (3.2, 4.2)*.	
☐	Date of most recent version of consent document is shown.	
☐	Printed copies of survey instruments submitted (3.2, 11.9)*.	
☐	Printed copy of Study Protocol submitted (3.2, 7.1)*.	
☐	Printed copies of solicitation materials for subject recruitment submitted (3.2, 6.4)*.	
* Indicates these documents are required when these sections of the application form apply		

FOR MDCH IRB OFFICE USE ONLY:

Date Submitted:		Processed by:	
Decision final:			
Notice sent:		Review time:	

The Department of Community Health is an equal opportunity employer, services, and programs provider.